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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: James P. Elia)

Serial No.: 09/064,000)

Filed: April 21, 1998)

For: METHOD FOR GROWTH
OF SOFT TISSUE)

Group Art Unit: 1646)

Examiner: Elizabeth C. Kemmerer, Ph.D.)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, in an envelope addressed to: MAIL STOP AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

APRIL 25, 2006
Michael H. White 4/25/06

Signature

Date

**PETITION TO THE DIRECTOR OF GROUP 1600
UNDER 37 C.F.R. §1.181**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

This Petition is filed under 37 C.F.R. §1.181 seeking review and resolution of the force of circumstances requiring: (1) Applicant to pay a \$510.00 Three-Month Extension of Time fee to perfect filing of a Notice of Appeal for this patent application; and (2) the inordinate delays involved in the prosecution of this patent application that have led to significant potential term erosion. Petitioner prays for relief in the form of a refund of the \$510.00 fee and in the form of the Director of Group 1600 (hereinafter "Director") invoking appropriate supervisory authority to insure that prosecution of this patent application proceed forward in accordance with established Patent and Trademark Office ("PTO") rules and guidelines to prevent further

unwarranted potential term erosion.

BASIS FOR PETITION

Petitioner believes that the Director's review of the above-mentioned circumstances is warranted because of the failure of the Examiner(s) in charge of this application to follow prescribed PTO regulations and guidelines. Such failure directly resulted in Applicant's having to tender an unnecessary payment for a three-month extension fee to avoid abandonment of this application and also resulted in potential, unnecessary term erosion.

More specifically, The Examiner's failure to issue a timely Advisory Action, i.e., an Advisory Action received by Petitioner's attorney within six months of the October 20, 2005 mailing date of the Final Rejection, resulted in Petitioner being needlessly required to file a Notice of Appeal at a short interval prior to the end of the six-month statutory period to avoid abandonment of the application. To perfect such Notice of Appeal, Petitioner was required to pay a \$510.00 extension fee that would not have been required had the Examiner followed established PTO regulations and guidelines and issued a timely Advisory Action.

The Final Rejection of October 20, 2005 contained the following form paragraph:

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed with TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Such failure is believed to be especially egregious considering that Petitioner, following the

guidelines of the above form paragraph, submitted a response within two months of the mailing date of the Final Rejection, and an Advisory Action was not received from the PTO before expiration of the six-month statutory period.

In view of the above-mentioned circumstances and the prosecutorial history of this application, Petitioner respectfully believes that a refund of the fee is justified and that invoking of the Director's supervisory authority is a necessary and appropriate prerequisite to prevent any further erosion of Petitioner's potential patent term. Also, as will be explained more fully below, the Examiner's lack of timeliness has resulted in further prejudice to Petitioner in the form of potential term erosion.

STATUS OF THE APPLICATION

Claims 382-394 stand finally rejected in the Final Rejection of October 20, 2005.

As of the mailing date of this Petition, Petitioner's attorney has not received an Advisory Action responsive to its Response After Final Rejection Under 37 CFR §1.113, filed December 2, 2005.

PROSECUTION HISTORY OF THE APPLICATION

The Application was filed on April 21, 1998 and claims priority under 35 U.S.C. §120 through a chain of applications to April 27, 1993. More specifically, this application is a continuation-in-part of application Serial No. 08/837,608, filed April 21, 1997, now abandoned, which is continuation-in-part of application Serial No. 08/326,857, filed October 21, 1994, now Patent No. 5,759,033, which is a continuation of application Serial No. 08/087,185, filed July 2, 1993, now Patent No. 5,397,235, which is a continuation-in-part of application Serial No. 08/053,886, filed April 27, 1993, now Patent No. 5,372,503. This application is entitled to be

accorded special status in accordance with PTO guidelines because of such effective filing date. The special status of the application was called to the Examiner's attention at page 16 in the Response to the Final Rejection of October 20, 2005, mailed on November 29, 2005 and served as a request for corrective action regarding the lack of timely action and consequent term erosion. Hence, the instant Petition serves as a further request for timely action.

The first action on the merits for the instant application was a rejection issued by Examiner Nicholas D. Lucchesi on May 27, 1999. Following Petitioner's response filed December 16, 1999, Examiner Lucchesi issued a non-Final Rejection on August 16, 2000. Petitioner responded to such rejection in an Amendment dated February 14, 2001. Examiner Lucchesi did not respond to this Amendment and instead is believed to have transferred jurisdiction of the application to Examiner Elizabeth C. Kemmerer sometime during the summer of 2003. The two and one-half year period of inaction while the case was under Examiner Lucchesi's jurisdiction included a six-month suspension of prosecution.

On September 15, 2003, Examiner Kemmerer acted on the application for the first time by making a 26-way restriction requirement on previously cancelled claims.

Petitioner responded to such restriction requirement on September 18, 2003 by pointing out that the claims subject to the restriction requirement had been canceled and submitted a copy of the Amendment containing the then currently pending claims.

On November 19, 2003, the Examiner vacated the September 15, 2003 restriction requirement and made a two-part species restriction.

Petitioner elected the species drawn to organic matter in the response of December 17, 2003.

In the February 24, 2004 action, the Examiner withdrew the original restriction requirement because of an apparent lack of understanding of the term "organic matter." The

Examiner erroneously believed that organic matter was “limited to small organic molecules, such as ring structures and not encompassing species listed in the requirement, such as the growth factor polypeptides of species d) – n).” Petitioner remains at a loss to understand how such an interpretation could have been placed on the term “organic matter” because no such ring-type structure was disclosed in the specification. Moreover, Petitioner does not understand how the Examiner could determine that polypeptides are not organic matter.

In any event, on March 3, 2004, Petitioner elected to prosecute claims to the sub-generic term or species, “living organism.” Petitioner also identified claims readable on such inventions as including claims to multifactorial and/or nonspecific living organisms. Multifactorial and/or nonspecific are disclosed in the specification as characteristics of growth factors comprising cells, such as stem cells. Please see page 37, lines 19-25 and page 49, line 28 through page 50, line 6.

In a subsequent Office Action dated June 3, 2004, the Examiner changed the restriction requirement yet another time by joining species o) –bacteria and species q) –virus, into species c) –living organism, and then rejected the all of the claims under 35 U.S.C. §101 and §112. During such rejection, the Examiner contended that the terms “multifactorial” and “nonspecific” were not used to describe living organisms in the art and that a living organism included bacteria and virus or any other living organism which promotes tissue growth and that a stem cell is not a living organism. Thus, in the Office Action, the Examiner excluded an embodiment (multifactorial and nonspecific growth factor, such as a stem cell) of the disclosed invention that was elected by Petitioner.

Petitioner responded to the June 3, 2004 Office Action on August 19, 2004 by pointing out the Examiner’s erroneous understanding of the above terms and, in an effort to obtain a first action on the merits of its elected invention, canceled the prior claims and presented a new set of

claims. Petitioner's responses (amendments) have consistently constituted a narrowing from the original growth factor genus while staying within the scope of the elected invention. Petitioner expected that such submissions would provoke a legitimate action on the merits.

Instead, the Examiner issued the Final Rejection on October 18, 2004, which basically repeated the errors of the previous Office Action.

At this point in the prosecution, including Examiner Lucchesi's inaction and six-month suspension and Examiner Kemmerer's procedural Office Actions that involved primarily restriction requirements, rather than actions on the merits, over three and one-half years expired without an Office Action on the merits being issued. This situation was considered especially troublesome to Petitioner because the three-year term extension guarantee, which applies to later-filed applications, does not apply to the instant application because Petitioner's April 21, 1998 filing date falls between June 8, 1995, and May 28, 2000. Thus, perforce, Petitioner was severely prejudiced in term length at such point in the prosecution by the long administrative delay by the PTO between the February 15, 2001 response and the Office Action of October 18, 2004. Furthermore, such delay was considered to have been compounded by the Final Rejection of October 18, 2004, which entered the newly presented claims directed to the elected invention but did not treat the subject matter of such newly presented claims.

In view of the above-enumerated circumstances, Petitioner filed a first Petition Under 37 C.F.R. §1.113 to Director of Group 1600 on November 5, 2004 (copy enclosed), seeking the following relief:

1. The Examiner be instructed to withdraw the objection to claims 382-388;
2. The Examiner be instructed to construe the restriction requirement in light of Petitioner's specification and in accordance with conventional medical terminology and thereby construe Petitioner's elected specie to include claims

382-388;

3. The Examiner be instructed to withdraw the Final Rejection as being premature and issue a new, non-final action on the merits for claims 382-388; and
4. Petitioner respectfully requests an oral hearing to further address this matter. It is suggested that Petitioner's attorneys, Gerald K. White and Charles N. Lovell, attend any hearing, along with Examiner Elizabeth C. Kemmerer, Ph.D., and the Supervising Primary Examiner, Brenda Brumback, Ph.D. Petitioner believes that a hearing could serve to place the application on track and also expedite its prosecution. This objective is especially important to Petitioner in view of the above-discussed term erosion situation.

After more than six months and being the subject of four (4) unanswered Status Letters, the first Petition was not formally answered but instead the Examiner issued a non-final Office Action on June 21, 2005. Such Office Action indicated that the first Petition was moot in view of the Office Action. Applicant believes that the Examiner was correct in stating that the first Petition was moot because the Office Action essentially resulted in the relief sought in the first Petition.

Petitioner responded to the June 21, 2005 Office Action on July 25, 2005.

The Examiner then issued a Final Rejection on October 20, 2005 in which all claims were rejected.

Petitioner responded to such Final Rejection on December 2, 2005, a time period of less than two months, thereby fully meeting the two-month time period specified in the Final Rejection for filing a first reply thereto. By meeting such criteria, Petitioner became entitled to an extension fee calculated from the date of mailing of the Advisory Action. However, no timely

Advisory Action was received, and Petitioner was therefore unable to benefit from such entitlement.

As considerable time passed without receiving an Advisory Action, Petitioner became concerned as to the status of the Advisory Action and attempted to determine such status in the following manner:

1. On March 9, 2006, a faxed Status Letter was filed. To date, no response has been received to such letter.
2. Not having received a response to the Status Letter, Attorney for Petitioner, Gerald K. White called Examiner Kemmerer on Monday, March 27, 2006 and was informed that she planned to work on an Advisory Action during the week of March 27, 2006.
3. Still not having received an Advisory Action, Mr. White followed-up the prior call and left a voice mail message for Examiner Kemmerer on April 12, 2006 inquiring about the status of the Advisory Action.
4. Examiner Kemmerer left a voice mail message for Mr. White at 5:37 a.m. on Monday, April 17, 2006, which stated she had been "out last week" and further stated that she had not acted on the Advisory Action. She further stated that, "it's been sitting on my desk, and I've had a number of other emergency cases come before me – some decisions by the Board – which my Group Director had me prioritize, even above the Specials, the After Finals." She also stated it was tops on her list this week, "as it's a new bi-week, and we'll be getting you that Advisory Action this week. I promise."

On April 18, 2006, Petitioner mailed a Notice of Appeal to ensure that the application would not become abandoned. The right to supplement the Notice of Appeal was reserved by Applicant because no Advisory Action had been received as of the date of April 18, 2006.

As of today's date, Petitioner's attorney has not received an Advisory Action.

REQUEST FOR REFUND OF EXTENSION OF TIME FEE

As is clearly evident from the above prosecutorial history, the PTO's failure to respond in a timely manner resulted in Petitioner having to pay an extension of time fee that would not have been required had the Examiner acted in a diligent manner following applicable PTO regulations and guidelines. First, the application was not treated in accordance with special status. Second, the lack of a timely Advisory Action runs counter to the PTO's obligation to issue timely Advisory Actions, especially when Petitioner responded to the Final Rejection within the prescribed two months and thus the PTO had ample time (over four months) to respond thereto prior to expiration of the six-month period. Inasmuch as the need to pay for an extension was caused by the PTO, despite several follow-up attempts by Petitioner, equitable relief in the form of a refund of the extension fee should be granted to Petitioner.

REQUEST TO INVOKE SUPERVISORY AUTHORITY

While the above-stated Prosecution History of the Application speaks for itself, it is clear that inordinate delays on the part of the PTO have occurred. There can be no doubt that such delays are potentially prejudicial to Petitioner regarding term erosion. Hence, Petitioner respectfully requests that the supervisory authority of the Director be invoked and that the Examiner be instructed to conduct prosecution in accordance with the special status priority to which this application is entitled. Such conduct should include requiring the Examiner to follow the tenets of compact prosecution. Essentially, all Petitioner is requesting is that the Examiner be instructed to adhere to and follow established PTO regulations and guidelines. Otherwise, Petitioner will continue to endure the erosion of potential patent term rights.


Petitioner is willing to attend an oral hearing to further address this matter should the Director deem a hearing to be useful. If a hearing is deemed useful, Petitioner suggests that its attorneys, Gerald K. White and Charles N. Lovell, attend any hearing, along with Examiner Elizabeth C. Kemmerer, Ph.D., and the Examiner's supervisor indicated on the Final Rejection, Anthony Caputa, Ph.D. Any hearing could serve to place the application on track and also expedite its prosecution, which is especially important to Petitioner in view of the above-discussed term erosion situation.

SUMMARY

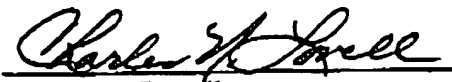
Petitioner hereby respectfully requests the relief requested above and any other relief as may be deemed appropriate by the Director to correct the above-enumerated complaints.

Respectfully submitted,

Date: April 25, 2006


Gerald K. White
Reg. No. 26,611
Attorney for Petitioner

Date: April 25, 2006


Charles N. Lovell
Reg. No. 38,012
Attorney for Petitioner

GERALD K. WHITE & ASSOCIATES, P.C.
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Chicago, IL 60606
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Email: gkwpatlaw@aol.com

Docket No. ~~XXXXXXXXXX~~ Case 1

Serial No. ~~XXXXXXXXXX~~ 09/064,000

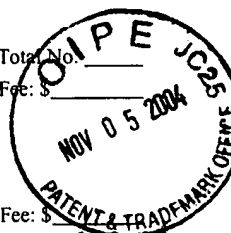
Filed ~~XXXXXXXXXX~~ 04/21/98

Due Date: - - -

The Patent Office acknowledges, and has stamped hereon, the date of receipt of the items check below:

- ☒ Transmittal Letter
- ☐ Application - Trademark
- ☐ Application - Patent Specification Total Pgs _____
- ☐ Total Claims _____ Ind. Claims _____ Total Pgs _____
- ☐ Abstract Total Pgs _____
- ☐ Drawings: Formal _____ Informal _____ Total Pgs _____
- ☐ Declaration/Oath/Power of Attorney Total Pgs _____
- ☐ Check No. _____ Fee: \$ _____
- ☐ Assignment and Cover Sheet Fee: \$ _____
- ☐ Request for Non-Publication
- ☐ Information Disclosure Statement
- ☐ Form PTO-1449 w/Refs _____ Total No. _____
- ☐ Request for Extension of Time Fee: \$ _____
- ☐ Amendment/Response
- ☐ Affidavit/Declaration/Statement
- ☐ Brief/Reply Brief/Notice of Appeal
- ☐ Fee-Base/Maintenance Fee: \$ _____

☒ Check No. 766 Fee: \$ 130.00
☒ Petition to Director of Group 1600
☒ Exhibits A-D



In The United States Patent and Trademark Office

In re application of: James P. Elia

Group No.: 1646

Serial No.: 09/064,000

Examiner: Elizabeth C. Kemmerer, Ph.D.

Filed: April 21, 1998

For: METHOD FOR GROWTH OF SOFT TISSUE

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: DIRECTOR OF GROUP 1600

1. Transmitted herewith is a Petition to Director of Group 1600 for this application.

2. Applicant is a small entity.

3. Fee Payment Being Made at This Time

☒ Enclosed

☒ filing fee (Petition to Director)

Total Fee paid at this time \$ 130.00

4. Method of Payment of Fees

☒ Check No. 766 in the amount of \$ 130.00

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

Reg. No.: 26,611



Signature of attorney

Gerald K. White

Type or print name of attorney

Tel. No.: (312) 920-0588

GERALD K. WHITE & ASSOCIATES, P.C.
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of: James P. Elia)	
)	Group Art Unit: 1646
Serial No.: 09/064,000)	
)	Examiner: Elizabeth C. Kemmerer, Ph.D.
Filed: April 21, 1998)	
)	
For: METHOD FOR GROWTH)	
OF SOFT TISSUE)	

PETITION UNDER 37 C.F.R. §1.113 TO DIRECTOR OF GROUP 1600

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

This Petition is filed under 37 C.F.R. §1.113 seeking review and resolution of the Examiner's objection to claims 382-388, all the claims in the subject application. Petitioner prays for relief in the form of the withdrawal of such objection and the issuance of a complete action on the merits of the invention of claims 382-388.

BASIS FOR PETITION

Petitioner believes that the Director's review of Examiner's objection to claims 382-388 is justified based upon the Examiner's misunderstanding of Petitioner's invention, which is manifested by the Examiner's mischaracterization and lack of understanding of the terms "living organism," "multifactorial," and "nonspecific" as they relate to the claimed invention.

The Examiner's entering of claims 382-388, and then effectively not examining the subject matter of such claims, renders it difficult, if not impossible, to respond to the Examiner's final rejection. The Examiner erred procedurally by treating the newly entered claims as if these claims were drawn to subject matter contained in canceled claims. Petitioner believes that any appeal to the Board of Patent Appeals and Interferences would necessarily raise jurisdictional issues and result in a remand for clarification of the status of claims 382-388. Accordingly, resolution of the objection by the Director of Group 1600 is a prerequisite to the further, meaningful prosecution of the instant application.

STATUS OF THE APPLICATION

Claims 382-388 (attached hereto as Exhibit A) are the only claims pending in the subject application. These claims were first presented in Petitioner's response of August 18, 2004, and were entered by the Examiner. In the Examiner's October 18, 2004 Final Office Action, these claims were finally rejected on technical grounds and also were objected to for allegedly reading upon non-elected inventions. The Examiner did not enter a prior art rejection against any claim. Petitioner believes that the Final Rejection is premature because no action, let alone a first action, was made on the merits of the subject matter of claims 382-388.

PROSECUTION HISTORY OF THE APPLICATION

The first action on the merits for the instant application was a rejection issued by Examiner Nicholas D. Lucchesi on May 27, 1999. Following Petitioner's response filed December 16, 1999, Examiner Lucchesi issued a non-Final Rejection on August 16, 2000. Petitioner responded to such rejection in an Amendment dated February 14, 2001. Examiner Lucchesi did not respond to this Amendment and instead is believed to have transferred

jurisdiction of the application to Examiner Elizabeth C. Kemmerer sometime during the summer of 2003. The two and one-half year period of inaction while the case was under Examiner Luccehsi's jurisdiction included a six-month suspension of prosecution. On September 15, 2003, Examiner Kemmerer acted on the application for the first time by making a 26-way restriction requirement on previously cancelled claims. Petitioner responded to such restriction requirement on September 18, 2003 by pointing out that the claims subject to the restriction requirement had been canceled and submitted a copy of the Amendment containing the pending claims. On November 19, 2003, the Examiner vacated the September 15, 2003 restriction requirement and made a two-part species restriction. Petitioner elected the species drawn to organic matter in the response of December 17, 2003. In the February 24, 2004 action, the Examiner withdrew the original restriction requirement because of an apparent lack of understanding of the term "organic matter." The Examiner erroneously believed that organic matter was "limited to small organic molecules, such as ring structures and not encompassing species listed in the requirement, such as the growth factor polypeptides of species d) – n)." Petitioner remains at a loss to understand how such an interpretation could have been placed on the term "organic matter" because no such ring-type structure was disclosed in the specification. Moreover, Petitioner does not understand how the Examiner could determine that polypeptides are not organic matter. On March 3, 2004, Petitioner elected to prosecute claims to the sub-generic term or species, "living organism." Petitioner also identified claims readable on such inventions as including claims to multifactorial and/or nonspecific living organisms. Multifactorial and/or nonspecific are disclosed in the specification as characteristics of growth factors comprising cells, such as stem cells. Please see page 37, lines 19-25 and page 49, line 28 through page 50, line 6. In a subsequent Office Action dated June 3, 2004, the Examiner changed the restriction requirement yet another time by joining species o) –bacteria and species q) –virus into species c)

-living organism and then rejected the all of the claims under 35 U.S.C. §101 and §112. During such rejection, the Examiner contended that the terms "multifactorial" and "nonspecific" were not used to describe living organisms in the art and that a living organism included bacteria and virus or any other living organism which promotes tissue growth and that a stem cell is not a living organism. Thus, in the Office Action the Examiner excluded an embodiment (multifactorial and nonspecific growth factor, such as a stem cell) of the disclosed invention that was elected by Petitioner. Petitioner responded to the June 3, 2004 Office Action on August 19, 2004 by pointing out the Examiner's erroneous understanding of the above terms and, in an effort to obtain a first action on the merits of its elected invention, canceled the prior claims and presented a new set of claims. Petitioner's responses (amendments) have consistently constituted a narrowing from the original growth factor genus while staying within the scope of the elected invention. Petitioner expected that such submissions would provoke a legitimate action on the merits. Instead, the Examiner issued the Final Rejection on October 18, 2004, which basically repeated the errors of the previous Office Action.

Including Examiner Lucchesi's inaction and six-month suspension and Examiner Kemmerer's procedural Office Actions that involve primarily restriction requirements, rather than actions on the merits, over three and one-half years have passed since the last Office Action on the merits was issued. The three-year term extension guarantee, which applies to later-filed applications, does not apply to the instant application because Petitioner's April 21, 1998 filing date falls between June 8, 1995, and May 28, 2000. Thus, perforce, Petitioner has already been severely prejudiced in term length by the long administrative delay by the PTO between the February 15, 2001 response and the Office Action of October 18, 2004. Furthermore, this delay has been compounded by the outstanding Final Rejection, which does not appear to treat the elected invention.

EXAMINER'S OBJECTION TO CLAIMS 382-388

In objecting to claims 382-388, the Examiner stated that the claims read on non-elected inventions. As will be demonstrated below, the claims, in fact, read upon the invention elected by Petitioner; and the Examiner's position is flawed due to a fundamental lack of understanding of and a mischaracterization of the terms "multifactorial" and "nonspecific" as well as "living organism." Petitioner believes that the Examiner's objection is inextricably linked to a series of restriction requirements and a failure of the Examiner to consider the written disclosure when reviewing the claims for compliance with the requisite patent regulations and statutory requirements.

At page 37, lines 19-25 and at page 49, line 28 through page 50, line 6 of the specification, it is clear that the terms "multifactorial" and "nonspecific" are utilized as adjectives to characterize growth factors, such as stem cells. This fact is included in the Fifth Supplemental Information Disclosure Statement ("IDS") filed October 21, 2004, (attached hereto as Exhibit B), which crossed in the mail with the October 18, 2004 Final Rejection. It is beyond reasonable dispute that one reading the dictionary references in the IDS would conclude that "multifactorial" and "nonspecific" are adjectives denoting characters and qualities of cells.

The Examiner, in the Final Rejection, alleged that the art only uses such terms to describe causes, effects, and processes. Obviously, such allegation flies in the face of conventional medical terminology. These terms are used throughout Petitioner's specification in a manner consistent with the definitions contained in Exhibit B. The Examiner's erroneous understanding of these terms goes to the core of the issue as to whether or not the present claims are embraced by the elected invention.

The Examiner's second major technical misunderstanding is in alleging that stem cells are not living organisms. In fact, the Examiner stated at page 6 of the Final Rejection that,

“While Petitioner may be his own lexicographer, to define a living organism as encompassing stem cells is repugnant to the meaning of ‘living organism’ found in the art. Such is improper.” The Examiner also alleged that, “...the art defines ‘living organism’ as independent,” and that, “Stem cells are part of a living organism, but are not living organisms, per se.” All of the above allegations are factually incorrect and at variance with accepted usage in the medical arts to which the present invention is directed. What we have here is a case where the Examiner chose to become her own lexicographer rather than simply considering such terms in light of Petitioner’s specification and highly reputable medical publications.

In the Response of August 18, 2004, Petitioner provided evidence that cells are living organisms. That stem cells are clonogenic and clones are living organisms are such well-established biological tenets, that official notice should be taken of these facts. In any event, clonogenic means the cells generate identical copies of themselves. Based on the aforesaid information cited in the Response, it is irrefutable that cells, including stem cells, are living organisms. The Examiner responded to this statement by agreeing that the term “clone” can refer to pieces of nucleic acid, cells, or entire living organisms but did not accept this evidence on the basis that cells, while alive, are not necessarily a living organism. The Examiner further stated that living organisms must be independent. In addressing this issue, the Examiner admits the well-established fact that cells are clones. If clones are living organisms, cells must also be living organisms because cells routinely clone. Moreover, the On-line Medical Dictionary published at the Dept. of Medical Oncology, University of Newcastle upon Tyne (attached hereto as Exhibit C) includes the following definition:

Clone – a propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

Obviously, from this definition, a living organism can consist of a single cell.

In any event, the glossary posted on the Biospace website, www.biospace.com (attached hereto as Exhibit D), contains a definition of "cell" provided by the National Institutes of Health and demonstrates that a single cell is a living organism. The definition is as follows:

Cell – it is a small, watery membrane-bound compartment filled with chemicals and a complete copy of the organism's genome. All living organisms are made of one or more cells.

The above definitions clearly evince that the Examiner's narrow definition of "living organism" is contrary to knowledge understood in the medical arts.

The Examiner has patently mischaracterized the nature and meaning of the well-recognized medical terms "multifactorial," "nonspecific," and "living organism." The Examiner's multifarious restriction requirements based upon technically inaccurate information have further prolonged prosecution and are tantamount to denying Petitioner procedural due process. Giving the above terms their correct medical meaning, it is clearly evident that claims 382-388 fall within Petitioner's elected invention and that an action examining such claims should have been provided by the Examiner. Petitioner believes that it is entitled to a full, complete action on the merits of such claims.

In view of the above remarks and evidence, Petitioner hereby respectfully requests the following relief:

1. The Examiner be instructed to withdraw the objection to claims 382-388;
2. The Examiner be instructed to construe the restriction requirement in light of Petitioner's specification and in accordance with conventional medical terminology and thereby construe Petitioner's elected specie to include claims 382-388;

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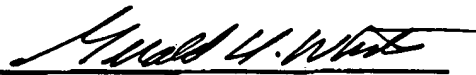
NO. 025 P. 2

PATENT APPL. NO. 09/064,000


3. The Examiner be instructed to withdraw the Final Rejection as being premature and issue a new, non-final action on the merits for claims 382-388; and
4. Petitioner respectfully requests an oral hearing to further address this matter. It is suggested that Petitioner's attorneys, Gerald K. White and Charles N. Lovell, attend any hearing, along with Examiner Elizabeth C. Kemmerer, Ph.D., and the Supervising Primary Examiner, Brenda Brumback, Ph.D. Petitioner believes that a hearing could serve to place the application on track and also expedite its prosecution. This objective is especially important to Petitioner in view of the above-discussed term erosion situation.

Respectfully submitted,

Date: November 4, 2004


Gerald K. White
Reg. No. 26,611
Attorney for Petitioner

Date: November 4, 2004


Charles N. Lovell
Reg. No. 38,012
Attorney for Petitioner

GERALD K. WHITE & ASSOCIATES, P.C.
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Email: gkwhite@att.net

382. A method for producing a desired soft tissue in a body of a human patient comprising:

- (a) Placing cells in said body of said human patient;
- (b) Forming a bud in said body of said human patient; and
- (c) Growing said desired soft tissue from said bud.

383. The method of claim 382, wherein said cells are multifactorial and non-specific.

384. The method of claim 383, wherein said cells comprise stem cells.

385. The method of claim 382 further comprising forming a new artery.

386. The method of claim 383 further comprising forming a new artery.

387. The method of claim 382, wherein said soft tissue comprises mesodermal tissue.

388. The method of claim 382, wherein said soft tissue comprises an artery.

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 TO: Auto-reply fax to 312 920 0580 COMPANY:

Auto-Reply Facsimile Transmission



TO:

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DATE: October 21, 2004 NO. OF PAGES: 7
 TO: Commissioner of Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450
 ATTN: Examiner Elizabeth Kemmerer, Ph.D.
 Art Unit 1646
 FAX NO.: (703) 872-9308
 FROM: Gerald K. White
 RE: Patent Application Serial No. 09/064,000
 Applicant: James P. Ella
 Filed: April 21, 1998
 Title: METHOD AND APPARATUS FOR
 INSTALLATION OF DENTAL IMPLANT

Sir:

Enclosed is Applicant's Fifth Supplemental Information Disclosure Statement (including Certification), Form PTO-1449 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).

Respectfully submitted,

Gerald K. White
 Reg. No. 28,611
 Attorney for Applicant

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TO: Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

ATTN: Examiner Elizabeth Kemmerer, Ph.D.
Art Unit 1646

FAX NO.: (703) 872-9306

FROM: Gerald K. White

RE: Patent Application Serial No. 09/064,000
Applicant: James P. Elia
Filed: April 21, 1998
Title: METHOD AND APPARATUS FOR
INSTALLATION OF DENTAL IMPLANT

Sir:

Enclosed is Applicant's **Fifth Supplemental Information Disclosure Statement** (including Certification), Form PTO-1449 (Modified), and a copy of each publication listed thereon (References ABY and ABZ).

Respectfully submitted,



Gerald K. White
Reg. No. 26,611
Attorney for Applicant

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia)	
)	Group Art Unit: 1646
Serial No.: 09/064,000)	
)	Examiner: Elizabeth Kemmerer, Ph.D.
Filed: April 21, 1998)	
)	
For: METHOD AND APPARATUS)	
FOR INSTALLATION OF)	
DENTAL IMPLANT)	

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

Sir:

Enclosed herewith, please find Form PTO-1449 (Modified) pertaining to the above-identified application. A copy of each of the publications listed thereon (References ABY₁-ABZ) is enclosed.

This Fifth Information Disclosure Statement (IDS) is submitted to address an issue raised by the Examiner regarding the meaning of the terms "multifactorial" and "nonspecific cells." While Applicant believes that it has used such terms properly and that one skilled in the art would fully comprehend the meaning of such terms, dictionary definitions are included to further acquaint the Examiner with such terms as they are used in the medical arts.

As will be noted from References ABY and ABZ, "multifactorial" and "nonspecific" are adjectives that denote qualities and characterizations of cells.

"Multifactorial" means: "involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)"

"Nonspecific" means: "...undestined, undetermined, undifferentiated,..."

It is clear from a reading of the patent application, the qualities and characteristics of multifactorial and nonspecific cells can be found in cells such as: stem cells, germinal cells, and pluripotent cells.

No one skilled in the art would question that a fundamental property of all of these cells is that they are undifferentiated.


Also, no one skilled in the art would question that the state of being known as "pluripotent" permits a cell to be capable of affecting more than one organ or tissue. A cell's capability to affect more than one tissue or organ involves or depends upon several factors or causes and can result from the interaction of many genes.

This IDS is being submitted in an effort to reduce the number of issues in the instant application and thereby expedite the prosecution thereof.

No fee is believed to be due because Applicant and Applicant's attorney were not aware of such patent more than three (3) months prior to this submission. A certification including such facts is enclosed.

Respectfully submitted,

Date: October 21, 2004



Gerald K. White
Reg. No. 26,611



PATENT
Appl. No. 09/064,000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: James P. Elia)	
)	Group Art Unit: 1646
Serial No.: 09/064,000)	
)	Examiner: Elizabeth Kemmerer, Ph.D.
Filed: April 21, 1998)	
)	
For: METHOD AND APPARATUS)	
FOR INSTALLATION OF)	
DENTAL IMPLANT)	

CERTIFICATION

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450


Sir:

I, Gerald K. White, Attorney for Applicant, hereby state that the two references cited in this Fifth Supplemental Information Disclosure Statement ("IDS") were first discovered by me less than three (3) months prior to the date set forth below.

I further state that no item of information contained in this Fifth Supplemental IDS was cited in a written communication from a foreign patent office in a counterpart foreign application, and, to my knowledge, after making reasonable inquiry, no item of information contained in this Fifth Supplemental IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three (3) months prior to the filing of this statement.

Respectfully submitted,

Date: October 21, 2004



Gerald K. White
Reg. No. 26,611

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Applicant's 5th Supplemental Information Disclosure Statement
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Form PTO-1449 (Modified)
(Use several sheets if necessary)



Docket No.:

Serial No.: 09/064,000

Filing Date: April 21, 1998

Applicant: James P. Elia

Group No.: 1646

Examiner: Elizabeth Kemmerer, Ph.D.

Reference Designation U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Sub-Class	Filing Date (if appropriate)

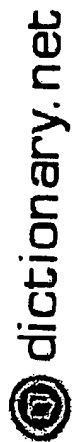
Foreign Patent Documents

Document Number	Date	Country	Class	Sub-Class	Translation Yes	No

Other Art (including author, title, date, pertinent pages, etc.)

ABY	http://www.dictionary.net definition of "multifactorial"
ABZ	http://www.dictionary.net definition of "nonspecific"

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



What does multifactorial mean?

multifactorial *adj* : involving or depending on several factors or causes (especially pertaining to a condition or disease resulting from the interaction of many genes)

Source: WordNet (r) 2.0

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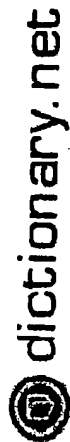
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What does nonspecific mean?

nonspecific adj : not caused by a specific agent; used also of staining in making microscope slides: "nonspecific enteritis" [ant. specific, specific]

Source: WordNet (r) 2.0

58 Moby Thesaurus words for "nonspecific": abstract, aleatory, amorphous, bland, blabby, blurred, blurry, broad, chance, chancy, chaotic, collective, confused, disordered, featureless, foggy, fuzzy, general, generalized, generic, hazy, hit-or-miss, ill-defined, imprecise, inaccurate, inchoate, incoherent, indecisive, indefinable, indefinite, indeterminate, indistinguishable, indistinct, inexact, lax, loose, nebulous, neutral, obscure, orderless, random, shadowed forth, shadowy, shapeless, stochastic, sweeping, uncharacterized, undear, undefined, undetermined, undifferentiated, unplain, unspecified, vague, veiled, wide

Source: Moby Thesaurus II by Grady Ward, 1.0

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clone from On-line Medical Dictionary

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clone

<cell biology> A propagating population of organisms, either single cell or multicellular, derived from a single progenitor cell. Such organisms should be genetically identical, though mutation events may abrogate this.

(18 Nov 1997)

Previous: clonal expansion, clonal selection, clonal selection theory, clonazepam

Next: clone bank, clone cells, clones, clones, recombinant, clonic

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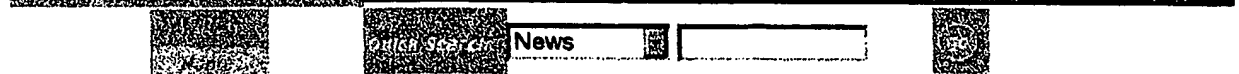
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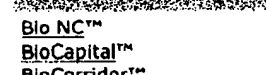
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Cell BASIC

The basic unit of any living organism.

Full Definition

It is a small, watery, membrane-bound compartment filled with chemicals and a complete copy of the organism's genome. All living organisms are made of one or more cells.

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